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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/783,836 02/14/01 DAVIES

P 9596.92U1 (K

000570 HM12/0717
AKIN, GUMP, STRAUSS, HAUER & FELD, L.L.P.
ONE COMMERCE SQUARE
2005 MARKET STREET, SUITE 2200
PHILADELPHIA PA 19103

EXAMINER

KETTER, J

ART UNIT

PAPER NUMBER

1636

DATE MAILED:

07/17/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/783,836

Applicant(s)

DAVIES ET AL.

Examiner

James Ketter

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,5-7,10,12,18,21,22,24 and 26 is/are rejected.
- 7) ☒ Claim(s) 2-4,19 and 23 is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

ZETA ADAMS
PATENT ANALYST

Z.A.

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:



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Claims 2-4, 19 and 23 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1, 5-7, 10, 12, 18, 21 and 22 are rejected under 35 U.S.C. 102(e) as being anticipated by Falb et al. (A).

The instant claims are drawn to a method of identifying a gene regulated by hydrodynamic (shear) stress, comprising placing a vascular endothelial cell, most narrowly claimed as a human cell, also more narrowly recited as being from a monolayer culture, under hydrodynamic stress, detecting the level of expression of the gene, and comparing said level to a negative control, i.e., measuring differential expression.

Falb et al. teaches, e.g., at column 4, lines 6-22, column 11, lines 17-35 and column 15, lines 26-39, using differential screening to detect differentially expressed genes, taught at column 14, lines 21-32 as being HUVEC cells grown under laminar shear stress in a monolayer. With respect to claim 21, Falb et al. teaches, e.g., at column 25, lines 39-56, the use of a gene

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regulated by hydrodynamic stress to isolate other such genes by hybridization. Such would be a method of directly comparing sequences. With respect to claim 10, Falb et al. teaches that the method may be practiced for diagnosis of disease states, e.g., as set forth in the Abstract. Such practice would require isolation of the endothelial cells from the patient to be diagnosed.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 8, 9, 11, 13-18, 20, 22, 24 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Falb et al. (A) in view of Eberwine (B).

The instant claims are drawn to a method of identifying a gene regulated by hydrodynamic (shear) stress, comprising placing a vascular endothelial cell, most narrowly

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claimed as a human cell, also more narrowly recited as being from a monolayer culture, under hydrodynamic stress, detecting the level of expression of the gene, and comparing said level to a negative control, i.e., measuring differential expression, wherein detection is performed for a single cell, recited most narrowly as employing amplified antisense in combination with northern blotting. Claim 26 is drawn to a kit comprising the recited reagents for such a method.

Falb et al. teaches, e.g., at column 4, lines 6-22, column 11, lines 17-35 and column 15, lines 26-39, using differential screening to detect differentially expressed genes, taught at column 14, lines 21-32 as being HUVEC cells grown under laminar shear stress in a monolayer. Falb et al. differs from the claimed invention in not teaching detection of the differential expression in a single cell, particularly employing amplified antisense and northern blotting for such detection.

Eberwine teaches, generally, the detection of gene expression from a defined gene in a single cell, using the amplified antisense method. Such detection is also taught in combination with northern blot detection of expression of said gene, e.g., at Example 4, bridging columns 11 and 12.

It would have been obvious to one of ordinary skill in the art to have modified the differential gene expression screening methods of Falb et al. by employing the amplified antisense and northern blotting detection methods taught by Eberwine. The motivation to use the Eberwine method for differential gene expression screening would have come from Eberwine, e.g., at column 3, first paragraph, and at the abstract, wherein it is taught that the method may be used to characterize cells at the molecular level. One of ordinary skill in the art thus would have recognized the applicability of the Eberwine method to the detection methods of Falb et al. With respect to claim 26, the grouping together of reagents useful together would have been obvious,

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as kits for the practice of methods both within and without the biotechnology art are and were well known prior to the instant invention.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 25 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant invention is drawn to an array comprising nucleic acid sequences identified by the recited method. However, the sequences were not necessarily known sequences, hence the usefulness of the recited method. As such, the claimed invention would encompass a great number of embodiments wherein one or more of the recited nucleic acids was of a sequence not set forth in the specification. While sequences corresponding to those recited are exemplified in the specification, said sequences do not possess any clear pattern to their respective structures. As such, they could not have constituted a representative sample of nucleic acids as recited in the instant claim. Since there would have been no way to predict the sequence of a gene merely from the general function of the protein encoded thereby, given the lack of a significant understanding of structure-function relationships for proteins in the art, Applicants

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would not have been able to convey to one of skill in the art that they were in possession of the claimed invention at the time of filing.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993)(see 37 CFR § 1.6(d)). The Art Unit 1636 Fax number is (703) 305-7939. NOTE: If Applicant *does* submit a paper by fax to this number, the examiner must be notified promptly, to ensure matching of the faxed paper to the application file, and the original signed copy should be retained by Applicant or Applicant's representative. (703) 308-4242 or (703) 305-3014 may be used without notification of the examiner, with such faxed papers being handled in the manner of mailed responses. Applicants are encouraged to use the latter two fax numbers unless immediate action by the examiner is required, e.g., during discussions of claim language for allowable subject matter. **NO DUPLICATE COPIES SHOULD BE SUBMITTED** so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner with respect to the examination on the merits should be directed to James Ketter whose telephone number is (703) 308-1169. The examiner can normally be reached on M-F (9:00-6:30) Alternate Fridays Off.

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Questions regarding formalities and processing of the case should be directed to Zeta Adams, whose telephone number is (703) 305-3291.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, John LeGuyader, can be reached at 308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-7939 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1234.

jsk
July 13, 2001



JAMES KETTER
PRIMARY EXAMINER